REMARKS

Claims 3, 4, 8, 9, 19-22, 25-26, 38-40, 42, 74-76, 78, 102, 104, 108, 112, 114 and 115 remain in this case.

Applicant has amended paragraph [0052] of the specification to describe what is inherently and explicitly disclosed in figures 3-3B and in the description of those figures. For example, figure 3A shows stent 104A within sleeve interior 124C while figure 3B illustrates tying the outer end 124F of graft material 124 indicating the flexible, movable nature of graft material 124.

Claims 4, 9, 19-22, 25, 26, 38-40, 74-76, 108, 111 and 113 are rejected under 35 USC 103(a) as being unpatenable over Dubrul (WO 98/47447) in view of Ragheb et al. (US 5873904).

Claim 3 is rejected under 35 USC 103(a) as being unpatenable over Dubrul (WO 98/47447) in view of Ragheb et al. (US 5873904) as applied to claim 40 and further in view of Scott (US 5,383,928).

Claim 8 is rejected under 35 USC 103(a) as being unpatenable over Dubrul (WO 98/47447) in view of Ragheb et al. (US 5873904) as applied to claim 38 and further in view of Kropf '849.

Claims 42, 78 are rejected under 35 USC 103(a) as being unpatenable over Dubrul (WO 98/47447) in view of Ragheb et al. (US 5873904) as applied to claim 38 and further in view of Khosravi '054.

Claims 102, 104, 112 and 114 are rejected under 35 USC 103(a) as being unpatenable over Dubrul (WO 98/47447) in view of Ragheb et al. (US 5873904) as applied to claims 38 and 74 and further in view of Hansen (US 5,399,352).

The Cited Art

The PCT published application to **Dubrul** has been cited as showing a helically coiled stent 50 with radially extending openings 51 which create open spaces were no portion of the coiled stent body would be. Dubrul has also been cited as showing a biologically active agent coating the stent and that the stent is made of metal.

Khosravi U.S. Patent No. 5,824,054 shows a graft stent 10 made of a coiled sheet 11 of lattice or mesh to which a biocompatible graft material 12 is affixed. Graft material may have a desired permeability and may be impregnated with one or more drugs to effect a desired treatment. (Column 4, lines 61-66.) Graft stent 10 is wrapped on to itself like a roll of tape. Figures 5A-5C show placement of graft stent 10 into a body lumen 100 to treat an aneurysm 101. The graft stent 10 is expanded by a

balloon 47 and is locked into its enlarged diameter configuration by teeth 15 engaging openings 16. (See figure 1 and column 5, lines 32-40.) The device is stated to be useful to "stem blood loss through an arterio-venous fistula, or provide a positive seal at the ends of a graft to reduce bypass flow." (Column 2, lines 31-35; column 3, lines 3-8.)

Hanson U.S. Patent No. 5,399,352 discloses a drug delivery device 10 comprising a first element 4 and a second element 24. The first element comprises an elongate tubular segment 5 comprising a porous clinical vascular graft attached at each end to a severed artery 2. Tubular segment 5 includes a porous portion 28. Porous portion 28 is surrounded by second element 24. A reservoir 20 is formed between porous portion 28 and second element 24. Reservoir 20 can be non-fillable or supplied with an agent through tubing 30. See column 7, line 32-column 8, line 20. This permits the agent to be delivered into the blood flowing through tubular segment 5 so that it can pass with the blood into the interior of the artery.

Kropf U.S. Patent No. 4,760,849 discloses a planar blank which can be made into a coil spring useful as a filter for thromboses. The coil spring has apertures to facilitate ingrowth of tissue into the spring material. See column 1, lines 61-63 and column 2, lines 51-55. This reference only discloses a stent. It teaches away from adding a graft material because a stated intention of the invention is to permit tissue ingrowth through the apertures. There is no recognition that the addition of a graft material would be useful or possible.

Ragheb U.S. Patent No. 5,873,904 discloses a medical device 10 including a structure 12, typically a vascular stent 12, composed of an elastic/non-elastic, biodegradable/non-biodegradable base material 14, such as stainless steel, nitinol, polymers, etc. Stent 12 is shown to have several layers of materials coated thereon. At least one layer 18 of a bioactive material is on the surface of stent 12. An outer porous layer 20 is on layer 18 to provide controlled release of the bioactive material. A porous/non-porous layer 16 may be used between the bioactive layer 18 and stent 12. A second bioactive layer 22 may be used between porous layer 20 and bioactive layer 18; if so, an inner porous layer 24 may be used between the bioactive layers 18, 22.

Scott U.S. Patent No. 5,383,928 has been cited as teaching a biodegradable polymer sleeve to control the delivery of bioactive drugs from the stent.

The Cited Art Distinguished

Claim 38 recites in part the following.

> "a coiled sleeve of porous material extending along the generally helical path, the material having an inner surface and an outer surface, the inner surface defining the sleeve interior containing the coiled body;
>
> the sleeve interior comprising regions occupied by the coiled body and open spaces not occupied by the coiled body; ...."

The Examiner states "Ragheb teaches to cover the stent with a sleeve to control release of the agents .... " Actually, Ragheb teaches coating the bioactive layer 18 with an outer porous layer 20 as opposed to containing the stent with then a sleeve.

Assuming, for sake of discussion, that it would have been obvious to use the teachings of Ragheb to cover the stent of Dubrul, the resulting structure would be, applicant submits, the stent of Dubrul covered with layers of material as taught by Ragheb. See, for example, figures 6A, 6B and 7 of Ragheb. In such a combination there would have been no open spaces not occupied by the stent. Therefore, the resulting structure would not have been the claimed invention including "the sleeve interior comprising regions occupied by the coiled body and open spaces not occupied by the coiled body; ...." There is nothing in these references suggesting such a structure.

Accordingly, claim 38 is allowable over the cited art. Independent **method claim 74** is allowable for similar reasons.

The **dependent claims** are directed to specific novel subfeatures of the invention and are allowable that reason is well as by depending from novel parent claims. For example, **claim 102** further specifies that "the sleeve interior is oversized relative to the coiled body so to loosely contain the coiled body." The suggested combination of the prior art would not result in such structure. While the Hanson patent may show a reservoir, there is nothing in that patent or the other cited art suggesting modifying the structure taught by Dubrul and Ragheb to arrive at the presently claimed invention. The mere fact that Hanson discloses external reservoir 20 provides no meaningful guidance for modifying the combination of Dubrul and Ragheb to a create open regions between the sleeve interior and the stent body of such a combination because the structure of Hanson relates to surrounding a perforated portion of a vascular graft; it has nothing to do with an endoluminal structure, such as a stent. They relate to two very different operating environments with very different operating constraints. Applicant contends that the Examiner has combined these references in a manner not supported by the facts. **Claim 104** is allowable for similar reasons. **Claim 114**, newly added, recites that at least part of the coiled body and the sleeve of porous material can move relative to one another. The combination taught by Dubrul and Ragheb would not

result in such a structure. There would have been no reason to modify the cited art to arrive at such a structure because there is nothing in the properly cited art suggesting the recognition that it would be desirable to do so. As discussed above, Hanson provides no appropriate guidance in this regard. **Claim 115** is allowable for similar reasons.

CONCLUSION

In light of the above remarks and the amendments to the claims, applicant submits that the application is in condition for allowance and action to that end is urged. If the Examiner believes a telephone conference would aid the prosecution of this case in any way, please call the undersigned at (650) 712-0340.

Respectfully submitted,

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James F. Hann, Registration No. 29,719

HAYNES BEFFEL & WOLFELD LLP
P.O. Box 366
Half Moon Bay, California 94019
Phone: 650-712-0340
Fax: 650-712-0263
JFH:plh